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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,635	01/29/2002	Shifeng Bill Wei	ORT-1585	7718

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AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
OH, SIMON J

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/059,635	Applicant(s) WEI ET AL.	
	Examiner Simon J. Oh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) 7-19 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). 3 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Papers Received

1. Receipt is acknowledged of the applicant's Information Disclosure Statement, received on April 22, 2002.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a substrate coating, classified in class 106, subclass 244^{+}.

II. Claims 7-14, drawn to a pharmaceutical composition, classified in class 424, subclasses 439^{+} and 439^{+}.

III. Claims 15-19, drawn to a method of depositing a coating, classified in class 427, subclasses 2.14^{+} and 472.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product (I) is deemed to be useful as either a pharmaceutical excipient in a tablet formulation or used in producing hybridoma cells utilizing a fusion technique, and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be coated with processes other than electrostatic deposition, such as spray drying, compaction, or fluidized bed techniques.

5. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention I merely relates to a substrate coating of a specific type of PEG, which may be used in a variety of techniques such as tableting or hybridoma cells utilizing a fusion technique. However, invention III relates to a coating process using an electrostatic deposition technique.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for

Group I is not required for Group II or Group II, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Ellen Coletti on May 23, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The parentheses within the claim render it indefinite because it is unclear whether the limitations are part of the claims.

10. Claim 1 also recites a film coating comprising or consisting essentially of polyethylene glycol with a particle size ranging from 1 to 100 microns. However, it is unclear how a film coating can comprise discrete particles.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan *et al.* (WIPO Document No. WO 96/35413)

The Hogan *et al.* document teaches a substrate coating for the electrostatic deposition of active substances (See Page 1, Lines 4-18; Page 3, Lines 3-27; and Page 5, Line 33 to Page 6, Line 11). The coating material preferably has a melting point of 50°C to 180°C (See Page 7, Lines 10-15). This material, in its powder form, has a particle size of less than 50 microns (See Page 8, Lines 7-16); and in one preferred embodiment, the powdered material has a mean particle size of about 10 microns, and substantially no particles larger than 100 microns in diameter (See Page 9, Lines 29-31). Polyethylene glycol with molecular weights of 20,000 and 6,000 are used in the coating material (See Example 1, Page 31, Lines 12-13; and Example 6, Page 34, Line 26). Additional components may be included in the coating material, including opacifiers, colorants, flavorants, and sweeteners (See Page 18, Lines 3-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan *et al.*, either alone or taken in view of Sturzenegger *et al.* (U.S. Pat. No. 4,197,289)

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Hogan *et al.* document teaches a substrate coating for the electrostatic deposition of active substances (See Page 1, Lines 4-18; Page 3, Lines 3-27; and Page 5, Line 33 to Page 6, Line 11). The coating material preferably has a melting point of 50°C to 180°C (See Page 7, Lines 10-15). This material, in its powder form, has a particle size of less than 50 microns (See Page 8, Lines 7-16); and in one preferred embodiment, the powdered material has a mean particle size of about 10 microns, and substantially no particles larger than 100 microns in diameter (See Page 9, Lines 29-31). Polyethylene glycol with molecular weights of 20,000 and 6,000 are used in the coating material (See Example 1, Page 31, Lines 12-13; and Example 6,

Page 34, Line 26). Additional components may be included in the coating material, including opacifiers, colorants, flavorants, and sweeteners (See Page 18, Lines 3-28).

The Hogan *et al.* application is silent with respect to the use of plasticizers in the coating material.

The Sturzenegger *et al.* patent discloses a pharmaceutical dosage form comprising an edible web upon which a powdered medicament can be deposited. The polymeric formulation of this web may include plasticizers (See Column 7, Lines 21-24) with which to modify the workability and the mechanical properties of the coating (See Column 8, Lines10-13). Glycerin is listed as a specific example (See Column 8, Lines 13-16).

Whether Hogan *et al.* is taken alone or in view of Sturzenegger *et al.*, the use of plasticizers in polymer coatings is known in the art. One of ordinary skill would desire to include a plasticizer in a polymer coating in order to modify its workability and mechanical properties to suit the needs of that particular dosage form. Thus, the invention as a whole is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Simon J. Oh
Patent Examiner
AU 1615

sjo
May 24, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600